

SECTION 5

BIOLOGICAL SAFETY PROGRAM

I. INTRODUCTION

A. The United States Department of Agriculture, Agricultural Research Service, and the Stuttgart/Pine Bluff Location (**SPBL**), which consists of the Aquaculture Systems Research Unit (ASRU, 1500 Oliver Road, Pine Bluff, AR 71601), the Dale Bumpers National Rice Research Center (DB NRRC, P.O. Box 1090, Stuttgart, AR 72160) and the Harry K. Dupree Stuttgart National Aquaculture Research Center (HKD SNARC, P.O. Box 1050, Stuttgart, AR 72160) are committed to the ideals of biological safety.

B. The general intent of the biological safety program for the **SPBL** is to:

1. Comply with the various local, state, and federal regulations that govern, either directly or indirectly, biological safety. Chief among these are:
 - a. Bloodborne Pathogens Rule, 29 Code of Federal Regulations (CFR) 1910.1030.
 - b. Additional Requirements for Facilities Transferring or Receiving Select Agents, 42 CFR 72.
2. Protect Location employees from health hazards associated with the use of biological agents in our laboratory.
3. Ensure that Location employees are not exposed to potentially harmful biological agents.
4. Identify, assess, and control potential biological hazards at the Location.

C. **Ahmed Darwish** is the **SPBL** Biological Safety Officer (BSO).

D. The plan will be available for all employees to review, and a copy will be located in the in each site library.

E. This plan will be reviewed annually by the BSO and updated as necessary.

II. REFERENCES

A. Biosafety is not regulated in a uniform manner. It is indirectly addressed by the general duty, accident reporting, personal protective equipment, and hazard communication regulations promulgated by the Occupational Safety & Health Administration (OSHA), and it is directly regulated by OSHA's Bloodborne, Pathogens Rule. The Environmental Protection Agency regulates management of hazardous waste, including biohazardous waste. It published National Technical Information Service Publication PB86-199130, *Guide for Infectious Waste Management*, in 1986. The National Institute of Occupational Health, National Institutes of Health, Centers for Disease Control and Prevention, Department of Transportation, and other Federal and State bodies have issued guidelines and recommendations in biosafety issues. The

Department of Health and Human Services' Additional Requirements for Facilities Transferring or Receiving Select Agents, 42 CFR 72, regulates the transfer of certain, listed "select agents", biohazardous agents that could be misused by terrorists.

B. Chapter DIV of ARS Manual 230.0, *ARS Safety, Health, and Environmental Management Program*.

C. U.S. Department of Health and Human Services, *Biosafety in Microbiological and Biomedical Laboratories*, 2nd ed., Washington, D.C., 1988.

III. DEFINITIONS - For the purpose of this plan, the following definitions will apply:

A. Biohazards: Biological hazards from plants, animals, or their products that may be infectious, toxic, or allergenic. Agents are bacteria, viruses, fungi, rickettsia, and parasites. The Centers for Disease Control and Prevention rank biohazards on a Biosafety Level (BL) of 1 to 5, with BL-1 designating the least hazardous biological organisms and BL-5 designating the most hazardous biological organisms:

1. BL-1 classifies defined and characterized strains of viable microorganisms not known to cause disease in healthy adult humans. *Bacillus subtilis*, *Naegleria gruberi* and infectious canine hepatitis are examples of BL-1 organisms.
2. BL-2 classifies the broad spectrum of moderate risk agents present in the community and associated with human disease of varying severity. BL-2 agents can be studied safely on the open bench if good microbiological techniques are in place and the potential for producing aerosols is low. *Salmonella typhimurium*, *Salmonella enteritidis*, Hepatitis B virus, and *Toxoplasma* spp. are examples of BL-2 organisms.
3. BL-3 classifies indigenous or exotic agents where the potential for aerosols is real and the disease may have serious or fatal consequences. *Mycobacterium tuberculosis*, *Coxiella burnetti*, and St. Louis encephalitis virus are examples of BL-3 organisms.
4. BL-4 classifies dangerous or exotic agents which pose high individual risks of life threatening disease. All manipulations of potentially infectious diagnostic materials, isolates, and naturally or experimentally infected animals pose a high risk of exposure and infection to Location personnel. Lassa fever virus is an example of a BL-4 organism.
5. BL-5 classifies foreign animal pathogens that are excluded from the United States by law or whose entry is restricted by the USDA.

B. Bloodborne Pathogens: Pathogenic microorganisms that are present in human blood or other potentially infectious materials and can cause disease in humans. These pathogens include, but are not limited to, hepatitis B virus (HBV) and human immunodeficiency virus (HIV). "Blood" means human blood, human blood components, and products made from human blood. "Other potentially infectious materials" means (1) semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any body fluid that is visibly contaminated with blood, and all

body fluids in situations where it is difficult or impossible to differentiate between body fluids any unfixed tissue or organ (other than intact skin) from a human (living or dead), (2) HIV-containing cell or tissue cultures, organ cultures, or (3) HIV-or HBV-containing culture medium or other solutions; and blood, organs, or other tissues from experimental animals infected with HIV or HBV.

C. Select Agent: A microorganism (virus, bacterium, fungus, rickettsia) or toxin listed in Appendix 5.4 of 42 CFR 72 that could be misused by terrorists.

D. Universal Precautions: An approach to infection control in which all human blood and certain human body fluids are treated as if known to be infectious for HIV, HBV, or other bloodborne pathogens.

IV. RESPONSIBILITIES

A. The ARS Biotechnology Research Oversight Committee (BROC) is responsible for:

1. Developing and implementing ARS policy and procedures for biotechnology research.
2. Providing oversight and coordination of ARS biotechnology research involving organisms classified at BL-3 or higher.
3. Ensuring ARS biotechnology research is performed in accordance with Federal biotechnology guidelines:
 - a. Resolving issues not specifically covered in biotechnology guidelines.
 - b. Reviewing unusual problems associated with biotechnology.
 - c. Reviewing protocols for environmental release of genetically engineered organisms.
 - d. Reviewing protocols involving organisms classified at BL-3 or higher.

B. The Location Coordinator is responsible for:

Current LC is Don Freeman

1. Approving, by signature, this plan.
2. Authorizing and supporting the implementation of this plan, the annual review of this plan, and amendments or changes to this plan.
3. Providing resources for training, equipment, and other support called for in this plan.

C. The Location Administrative Officer is responsible for:

Current LAO is Jeanie Gwathney (Acting)

1. Maintaining files and records of program activities.
2. Maintaining this plan
3. Publicizing this plan.

D. **Ahmed Darwish** is designated as the BSO for the **SPBL**. The BSO, acting in consultation with Location management, is responsible for:

1. Working with Research Leaders, scientists, and technical support staff to identify and assess potential biohazards and to develop effective control measures for those hazards.
2. Serving as a source of advice and counsel to all employees at the Location in the area of biosafety.
3. Working with researchers and the BROC if and when research involves recombinant DNA, biotechnology organisms classified by BROC as BL-3 or higher, or environmental release of genetically engineered organisms.
4. Providing or arranging appropriate training to employees regarding biohazards, safety controls, and emergency procedures at the Location.
5. Working with the Laboratory Director, Research Leaders, scientists, and Area technical personnel to maintain or design appropriate facilities, engineering features, and safety equipment.
6. Verifying, through periodic inspections, that Location standards are rigorously followed.
7. Reviewing this plan annually, in consultation with the Southern Plains Area Safety & Health Manager, to monitor its effectiveness.

E. Research Leaders, lead scientists, and department heads are responsible for:

1. Performing experiments or operations involving biological agents in accordance with established microbiological safety procedures, and ensuring that technical support personnel perform within those same procedures (See Appendix 5.2 and 5.3).
2. Maintaining appropriate authorizations and approvals, if required, from the BROC.
3. Ensuring employees comply with provisions of this plan.
4. Ensuring proper labeling, storage, use, transfer, and disposal of biological agents.

5. Ensuring proper signage in laboratories or other areas where potentially hazardous biological agents are being studied or are in use.
6. Ensuring that personnel wear appropriate personal protective equipment.
7. Ensuring that personnel have received proper training prior to initiating operations involving potentially hazardous biological agents.
8. Correcting work errors or conditions that may result in the release of biohazards.
9. Notifying the BSO and maintenance personnel when equipment or facilities critical to biosafety are inadequate or are not performing according to specification.

V. PROGRAM ELEMENTS

A. General Assumptions

1. At present, and for the foreseeable future, all **SPBL** research will be performed on BL-2 agents.
2. Research on organisms classified as bloodborne pathogens or as BL-3 or greater shall only be performed after consultation with and approval from the ARS Biotechnology Research Oversight Committee, the BSO, and the Area Safety & Health Manager.

B. General Principles of Biosafety

1. Containment prevents potentially hazardous biological agents from escaping into the environment and protects Location personnel and the public from accidental exposure to those agents.
2. Facility design helps protect Location personnel as well as the surrounding community from accidental exposure to biohazards.
 - a. **SPBL's** facilities, in common with most ARS laboratories, are designed for BL-1 and BL-2 agents.
 - b. Animal handling, waste staging, and laboratory areas are kept separate from public areas.
 - c. No research is presently performed at any of the **SPBL** sites, nor is it anticipated in the foreseeable future, which requires the use of BL-3 containment laboratories, or BL-4/BL-5 maximum containment laboratories.
 - d. Facility design considerations for BL-2 laboratories are outlined in Appendix 5.1 of this plan.

3. Microbiological laboratory practices: Strict adherence to standard microbiological laboratory practices provides protection against biohazards.
 - a. It is the responsibility of the research scientist to ensure that Location personnel are acquainted with and operating in accordance with sound laboratory practices.
 - b. Standard Operating Procedures for laboratory operations are contained elsewhere in the Location Laboratory Safety Program.
 - c. Standard and special microbiological practices for BL-2 laboratories are outlined in Appendix 5.2 of this plan.
4. Safety equipment is a primary barrier between personnel and potential biohazards. Types:
 - a. Enclosed containers prevent the release of aerosols or particulates into the work environment. Examples of enclosed containers are glove boxes and biological safety cabinets.
 - b. Personal protective equipment (e.g., respirators, gloves, coats, etc.) provides extra protection when performing work in enclosed containers. Personal protective equipment can provide the only protection when work in enclosed containers is impractical.
 - c. Safety equipment guidelines and other special practices are located in Appendix 5.3.

C. Prior Approval for Specific Laboratory Operations

1. When designing new experiments or operations with BL-2 organisms, researchers should notify their Research Leader and the BSO to determine what special procedures or approvals are necessary.
2. Research involving BL-3 organisms or higher must be reviewed and approved by the ARS BROCC.
3. Work with biohazards at the Location will be done in compliance with guidelines promulgated by the Agency and by the Centers for Disease Control and Prevention.

D. Medical Consultation

1. If an employee has been potentially exposed to a biohazard, or should an event take place in the work area that could potentially expose employees to biohazards (spill, leak, explosion, etc.), or should an employee develop signs and symptoms associated with biohazard exposure, the employee shall be provided the opportunity to receive

appropriate medical examination through the Chemical Hygiene Program (CHP). All CHP-related medical examinations and consultations are provided by the OHMP contractor, Stuttgart Regional Medical Center, N. Buerkle Rd., P.O. Box 1905, Stuttgart, AR 72160. These examinations are provided without cost to the employee, without loss of pay, and at a reasonable time.

2. If a work related illness or injury is apparent, the employee may file a Workers' Compensation claim, in which case medical services are provided by a physician of the employee's choice.
3. The BSO (or responsible supervisor) will provide the following information to the physician:
 - a. Identity of the biohazard to which the employee may have been exposed.
 - b. A description of the conditions of the exposure including exposure date if available.
 - c. A description of signs and symptoms of exposure that the employee is experiencing (if any).
4. Questions about the OMSP or workers' compensation program may be directed to the Personnel Specialist at the Area Administrative Office, 979-260-9443.

E. Disposal of Biohazard Waste

1. Biohazard waste is either autoclaved, incinerated, or both prior to final disposal.
2. Currently, only BL-2 level waste is generated on site. As such, following appropriate treatments (e.g. autoclaving, bleaching), waste materials are disposed of in the regular waste stream.
 - a. Biohazard waste (e.g. cultures, media, etc.) is autoclaved at 240 degrees Fahrenheit for at least one-half hour prior to being disposed.
 - b. Glove boxes and other reusable materials, which cannot be autoclaved, are sanitized by immersion or sponging in 50% bleach solutions. Immersion time should be several hours or overnight if possible.

VI. EMERGENCY PREPAREDNESS

A. Given the scale and types of biological experiments at the **SPBL** sites, it is unlikely that a biological emergency capable of causing serious harm to humans or the environment will occur.

B. The escape of experimental organisms, insects, or vertebrates used in normal research activities at the laboratories is not regarded as posing undue risk to humans or the environment.

C. The proper authorities should be notified in the event of a biological emergency (e.g., spillage of salmonella cultures, escape of salmonella treated animals):

1. Biological Safety Officer:
Ahmed Darwish (Work: 870-673-4483)
2. Research Leader \ Location Coordinator:
HKD SNARC: Dr. Don Freeman (Work: 870-673-4483 or
Cell: 870-830-7100)
3. Laboratory Director: Same as #2.

D. Location personnel should respond to biological emergency situations in a logical, reasonable manner consistent with their expertise and consistent with what would be expected of any reasonable private company employee, private citizen, or good neighbor.

1. Identify the biohazard.
2. Identify the potential range of biohazard exposure.
3. Initiate steps to protect humans, other animal life, or the environment in the area of potential biohazard exposure.
4. Recommend actions to responding authorities for controlling or protecting against the potential biohazard exposure.

VII. TRAINING

A. Employees working with biohazards will be provided with information and training so that they are acquainted with biohazards. This training will be performed as soon after the time of initial assignment as practicable and prior to new assignments. Refresher training will be given annually or as needed.

B. The training/information sessions shall include:

1. The availability and location of the written Biological Safety Plan.
2. Signs and symptoms associated with exposure to biohazards in the laboratories.
3. Location of reference materials regarding the safe handling of biohazards in the laboratories.

4. Methods to detect the presence or release of biohazards in the laboratories.
5. The physical and health hazards of biological agents in the laboratories.
6. Measures to protect employees from biohazards, including:
 - a. Standard operating procedures.
 - b. Location and use of biological safety cabinets, glove boxes, and other special equipment.
 - c. Work practices.
 - d. Personal protective equipment.
 - e. Emergency procedures.

C. The BSO is responsible for conducting or arranging the training sessions.

D. Each employee will sign a form documenting that they received training.

VIII. ANNUAL INSPECTION AND PROGRAM REVIEW

A. The BSO, in consultation with the Area Safety & Health Manager, will perform an inspection and program review at least annually to determine biological safety program compliance.

1. The inspection will verify that engineering controls, protective equipment, SOPs, workplace monitoring, and other aspects of the **SPBL** biosafety program are effective in preventing employee exposure to biohazards.
2. The review of the written program will determine the adequacy of the current **SPBL** program and whether changes, updates, or improvements are needed.

B. A copy of the inspection and review will be given to the Location Coordinator for correction of any discovered inadequacies or noncompliance.

C. A copy of the annual inspection will be kept in each **SPBL** site library, free for employee review.

IX. RECORDKEEPING AND REPORTING:

A. The following records will be kept:

1. Program activities.

2. Annual inspections and program reviews.

B. Records will be kept at each **SPBL** site library, free for employee review.

BLOODBORNE PATHOGENS PROTECTION PLAN

As a location that does not handle bloodborne pathogens, the **SPBL** does not fall under 29 CFR 1910.1030, the Bloodborne Pathogens Rule. Note: The following information is retained in the **SPBL** Safety Program in the event that the current status should change and for the general information of **SPBL** staff.

DEFINITIONS - For the purpose of this plan, the following definitions will apply:

1. Bloodborne Pathogens: Pathogenic microorganisms that are present in human blood or other potentially infectious materials and can cause disease in humans. These pathogens include, but are not limited to, hepatitis B virus (HBV) and human immunodeficiency virus (HIV). “Blood” means human blood, human blood components, and products made from human blood. “Other potentially infectious materials” means (1) semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids any unfixed tissue or organ (other than intact skin) from a human (living or dead), (2) HIV-containing cell or tissue cultures, organ cultures, or (3) HIV-or HBV-containing culture medium or other solutions; and blood, organs, or other tissues from experimental animals infected with HIV or HBV.
2. Decontamination: The use of physical or chemical means to remove, inactivate, or destroy bloodborne pathogens on a surface or item to the point where they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use, or disposal.
3. Regulated Waste: Liquid or semi-liquid blood or other potentially infectious materials; contaminated items that would release blood or other potentially infectious materials in a liquid or semi-liquid state if compressed; items that are caked with dried blood or other potentially infectious materials and are capable of releasing these materials during handling; contaminated sharps; and pathological and microbiological wastes containing blood or other potentially infectious materials.
4. Universal Precautions: An approach to infection control in which all human blood and certain human body fluids are treated as if known to be infectious for HIV, HBV, or other bloodborne pathogens.
5. Work Practice Controls: Controls that reduce the likelihood of exposure by altering the manner in which a task is performed (e.g., prohibiting recapping of needles by a two-handed technique).

I. PROGRAM ELEMENTS

1. Exposure Control Plan. Research Units that work with bloodborne pathogens shall write an exposure control plan. The plan shall be appended to the Biological Safety Program. The exposure control plan establishes criteria to eliminate or minimize employee exposure to

bloodborne pathogens and must contain at least the following elements

- a. The exposure determination.
 - 1) A list of job classifications and tasks, including custodial and maintenance, in which employees have occupational exposure to bloodborne pathogens.
 - 2) This exposure determination shall be made without regard to the use of personal protective equipment.
- b. Procedures for implementing
 - 1) Engineering and work practice controls.
 - 2) Medical monitoring.
 - 3) Hazard communication (labels, signs, and training).
 - 4) Recordkeeping.
- c. Procedures for evaluating the circumstances surrounding exposure incidents.

2. Labels and Signs

- a. Labels: Warning labels shall be affixed to containers of regulated waste, refrigerators and freezers containing blood or other potentially infectious material, and other containers used to store, transport or ship blood or other potentially infectious materials.
 - 1) The labels shall be fluorescent orange or orange-red, include the universal BIOHAZARD symbol, and the word “BIOHAZARD”, with symbol and lettering in a contrasting color.
 - 2) Labels shall be affixed as close as feasible to the container by string, wire, adhesive, or other method that prevents their loss or unintentional removal.
 - 3) Red bags or red containers may be substituted for labels.
 - 4) Containers of blood, blood components, or blood products that are labeled as to their contents and have been released for transfusion or other clinical use are exempted from these labeling requirements.
 - 5) Individual containers of blood or other potentially infectious materials that are placed in a labeled container during storage, transport, shipment or disposal are exempted from these labeling requirements.
 - 6) Contaminated portions of equipment shall be labeled in accordance with these requirements.
 - 7) Regulated waste that has been decontaminated need not be labeled or color-coded.

- b. Entrances to areas in which work is performed on bloodborne pathogens shall be posted with a sign, fluorescent orange or orange-red, with lettering and symbols in a contrasting color, containing at least the following information:
 - 1) Name of the Infectious Agent.
 - 2) Special requirements for entering the area.
 - 3) Name, telephone number of the laboratory director or other responsible person.
- 3. Methods to Reduce Exposure to Bloodborne Pathogens
 - a. Universal precautions shall be observed to prevent contact with blood or other potentially infectious materials. Under circumstances in which differentiation between body fluid types is difficult or impossible, all body fluids shall be considered potentially infectious materials.
 - b. Engineering and work practice controls shall be used to eliminate or minimize employee exposure. Where occupational exposure remains after institution of these controls, personal protective equipment shall also be used. Engineering controls shall be examined and maintained or replaced on a regular schedule to ensure their effectiveness.
 - c. Personal Hygiene
 - 1) Hand washing facilities shall be readily accessible to employees working with bloodborne pathogens. Employees shall wash their hands immediately or as soon as feasible after removal of gloves or other personal protective equipment. Employees shall also wash hands and any other skin with soap and water, or flush mucous membranes with water immediately or as soon as feasible following contact of such body areas with blood or other potentially infectious materials.
 - 2) If Hand washing facilities are not available, antiseptic hand cleanser in conjunction with clean cloth/paper towels or antiseptic towelettes shall be available. When these are used, hands shall be washed with soap and running water as soon as feasible afterwards.
 - d. Sharps
 - 1) Contaminated needles and other contaminated sharps shall not be bent, recapped, or removed unless:
 - a) No alternative is feasible or such action is required by a specific medical or dental procedure.
 - b) Such bending, recapping or needle removal is accomplished through the use of a mechanical device or a one-handed technique.
 - 2) Containers for non-reusable, contaminated sharps.

- a) These containers shall be easily accessible and located close to the immediate area where sharps are used or can be reasonably anticipated to be found. They will be kept upright throughout use, replaced routinely and not allowed to overfill.
 - b) When moving containers of contaminated sharps from the area of use, the containers shall be closed immediately prior to removal to prevent spillage or protrusion of contents during handling, storage, transport, or shipping, placed in a secondary container if leakage is possible. The container(s) shall be closable, constructed to contain all contents and prevent leakage during handling, storage, transport, or shipping, and labeled with the orange or orange-red biohazard symbol.
- 3) Containers for reusable sharps
 - a) Immediately or as soon as possible after use, contaminated reusable sharps shall be placed in appropriate containers until properly reprocessed.
 - b) These containers shall be puncture resistant, labeled with the orange or orange-red biohazard symbol, and leak proof on the sides and bottom. The containers shall be designed so employees do not need to reach into them to retrieve the sharps.
 - c) Reusable containers shall not be opened, emptied, or cleaned manually or in any other manner which would expose employees to the risk of injury.
- e. Ingestion Prevention
 - 1) Eating, drinking, smoking, applying cosmetics or lip balm, and handling contact lenses are prohibited in work areas where there is a reasonable likelihood of occupational exposure to bloodborne pathogens.
 - 2) Food and drink shall not be kept in refrigerators, freezers, shelves, cabinets or on countertops or benchtops where blood or other potentially infectious materials are present.
 - 3) All procedures involving blood or other potentially infectious materials shall be performed in such a manner as to minimize splashing, spraying, spattering, and generation of droplets of these substances.
 - 4) Mouth pipetting/suctioning of blood or other potentially infectious materials is prohibited.
- f. Storage, Processing, and Transportation of Containers or Equipment
 - 1) Specimens of blood or potentially infectious materials shall be placed in containers which prevent leakage during collection, handling, processing, storage, and transport.

- 2) The container for storage or transport shall be labeled with the orange or orange-red biohazard symbol and closed prior to being stored, transported, or shipped.
- 3) If outside contamination of the primary container occurs, the primary container shall be placed within a second container which prevents leakage during handling, processing, storage, or transport and is labeled with the orange or orange-red biohazard symbol.
- 4) If the specimen could puncture the primary container, the primary container shall be placed within a secondary container which is puncture-resistant in addition to the above characteristics.
- 5) Equipment which may become contaminated with blood or other potentially infectious materials shall be examined prior to servicing or shipping and shall be decontaminated.
 - a) If decontamination is not feasible, the potentially contaminated portions of the equipment shall be labeled with the orange or orange-red biohazard symbol.
 - b) All affected personnel shall be notified of contaminated equipment, prior to its handling, servicing, or shipping so that appropriate precautions will be taken.

g. Personal Protective Equipment.

- 1) During work with bloodborne pathogens, employees are required to wear personal protective equipment that prevents blood or other potentially infectious materials to pass through to or reach their work clothes, street clothes, undergarments, skin, eyes, mouth, or other mucous membranes. The laboratory will provide the equipment, and handle, as needed, its repair, replacement, cleaning, laundering, and disposal.
- 2) If a garment(s) is penetrated by blood or other potentially infectious materials, the garment(s) shall be removed immediately or as soon as feasible.
- 3) All personal protective equipment shall be removed prior to leaving the work area and placed in an appropriately designated area or container for storage, washing, decontamination or disposal.
- 4) Gloves. Gloves shall be worn when it can be reasonably anticipated that the employee may have hand contact with blood, other potentially infectious materials, mucous membranes, and non-intact skin; when performing vascular access procedures; and when handling or touching contaminated items or surfaces. Disposable (single use) gloves such as surgical or examination gloves, shall be replaced as soon as practical when contaminated or as soon as feasible if they are torn, punctured, or when their ability to function as a barrier is compromised. Disposable (single use) gloves shall not be washed or decontaminated for re-use. Utility gloves may be decontaminated for re-use if the integrity of the glove is not

compromised; however, they must be discarded if they are cracked, peeling, torn, punctured, or exhibit other signs that their ability to function as a barrier is compromised.

- 5) Masks, Eye Protection, and Face Shields. Masks in combination with eye protection devices, such as goggles or glasses with solid side shields, or chin-length face shields, shall be worn whenever splashes, spray, spatter, or droplets of blood or other potentially infectious materials may be generated and eye, nose, or mouth contamination can be reasonably anticipated.
- 6) Gowns, Aprons, and Other Protective Body Clothing. Appropriate protective clothing shall be worn in occupational exposure situations. The type and characteristics will depend upon the task and degree of exposure anticipated. Surgical caps or hoods and/or shoe covers or boots shall be worn in instances when gross contamination can reasonably be anticipated.
- 7) The location will make every effort to ensure that appropriate personal protective equipment in the appropriate sizes is readily accessible for employees. Hypoallergenic gloves, glove liners, powerless gloves, or other similar alternatives will be provided to employees who are allergic to the gloves normally provided.
- 8) EXCEPTION: There may be rare and extraordinary circumstances, usually in conjunction with first aid or a rescue, in which the considered professional opinion of the employee indicates that personal protective equipment would impede the delivery of health care or public safety services or would pose an increased hazard to the safety of an employee, co-worker, or member of the public. When an employee makes this judgement, the circumstances shall be investigated and documented in order to determine whether changes can be instituted to prevent recurrences.

h. Housekeeping.

- 1) The location shall ensure that facilities are maintained in a clean and sanitary condition
- 2) All equipment and environmental and working surfaces shall be cleaned with appropriate disinfectants as soon as reasonably feasible after contact with blood or other potentially infectious materials.
- 3) Protective coverings used to cover equipment and environmental surfaces shall be removed and replaced as soon as feasible after they become contaminated or at the end of the work shift if they may have become contaminated during the shift.
- 4) All bins, pails, cans, and similar receptacles intended for reuse which have a reasonable likelihood for becoming contaminated with blood or other potentially infectious materials shall be inspected and decontaminated on a regularly scheduled basis and cleaned and decontaminated immediately or as soon as feasible upon visible contamination.
- 5) Reusable containers such as trash cans shall not be opened, emptied, or

cleaned manually or in any other manner which would expose employees to the risk of percutaneous injury.

- 6) Broken glassware which may be contaminated shall not be picked up directly with the hands. It shall be cleaned up using mechanical means, such as a brush and dust pan, tongs, or forceps.
- 7) Regulated waste shall be placed in containers which are closable, constructed to contain all contents and prevent leakage of fluids during handling, storage, transport or shipping, labeled with the orange or orange-red biohazard symbol and closed prior to removal to prevent spillage or protrusion of contents during handling, storage, transport, or shipping. If outside contamination of the regulated waste container occurs, it shall be placed in another container meeting the same criteria as the first. Disposal of all regulated waste shall be in accordance with applicable regulations of the United States, States, Territories, and political subdivisions.

i. Laundry

- 1) Contaminated laundry shall be handled as little as possible with a minimum of agitation.
- 2) Contaminated laundry shall be bagged or containerized at the location where it was used and shall not be sorted or rinsed in the location of use.
- 3) Contaminated laundry shall be placed and transported in bags or containers labeled or color-coded in accordance with the orange or orange-red biohazard symbol. When a facility utilizes Universal Precautions in the handling of all soiled laundry, alternative labeling or color-coding is sufficient if it permits all employees to recognize the containers as requiring compliance with Universal Precautions.
- 4) Whenever contaminated laundry is wet and presents a reasonable likelihood of soak-through or leakage from the bag or container, the laundry shall be placed and transported in bags or containers, which prevent soak-through and/or leakage of fluids to the exterior.
- 5) Employees who have contact with contaminated laundry shall wear protective gloves and other appropriate personal protective equipment.
- 6) When a facility ships contaminated laundry off-site to a second facility which does not utilize Universal Precautions in the handling of all laundry, the facility generating the contaminated laundry must place such laundry in bags or containers which are labeled or color-coded with the orange or orange-red biohazard symbol.

II. TRAINING

1. In addition to the general training required under the location Biological Safety Program, personnel working with bloodborne pathogens will be provided with specific bloodborne pathogens training. This training will occur as soon after the time of initial assignment as practicable and prior to new assignments involving different exposure situations. Refresher

training will be given annually or more frequently as needed. The training/information sessions shall include:

- a. The contents of and meaning of the Bloodborne Pathogens standard and this plan.
 - b. A general explanation of the epidemiology and symptoms of bloodborne diseases.
 - c. An explanation of the modes of transmission of bloodborne pathogens.
 - d. An explanation of the location's exposure control plan.
 - e. An explanation of the appropriate methods for recognizing tasks and other activities that may involve exposure to blood and other potentially infectious materials.
 - f. An explanation of the use and limitations of methods that will prevent or reduce exposure including appropriate engineering controls, work practices, and personal protective equipment.
 - g. Information on the types, proper use, location, removal, handling, decontamination and disposal of personal protective equipment.
 - h. An explanation of the basis for selection of personal protective equipment.
 - i. Information on the hepatitis B vaccine, including information on its efficacy, safety, method of administration, the benefits of being vaccinated, and that the vaccine and vaccination will be offered free of charge.
 - j. Information on the appropriate actions to take and persons to contact in an emergency involving blood or other potentially infectious materials.
 - k. An explanation of the procedure to follow if an exposure incident occurs, including the method of reporting the incident and the medical follow-up that will be made available.
 - l. Information on the post-exposure evaluation and follow-up that the employer is required to provide for the employee following an exposure incident.
 - m. An explanation of the signs and labels and/or color-coding associated with this program.
 - n. An opportunity for interactive questions and answers with the person conducting the training session.
2. The BSO is responsible for conducting or arranging for training sessions.
 3. Each employee will sign a form documenting that they received training.

III. ANNUAL INSPECTION AND PROGRAM REVIEW

1. The BSO, in consultation with the Area Safety & Health Manager, will perform an inspection and program review at least annually to determine compliance with the Bloodborne Pathogens Protection Plan.

- a. The inspection will verify that engineering controls, protective equipment, SOPs, and other aspects of this plan are effective in preventing employee exposure to bloodborne pathogens.
 - b. The Exposure Control Plan shall be reviewed and updated at least annually and whenever necessary to reflect new or modified tasks and procedures which affect occupational exposure and to reflect new or revised employee positions with occupational exposure.
- 2. A copy of the inspection and review will be given to the Location Coordinator for correction of any discovered inadequacies or noncompliance.
- 3. A copy of the annual inspection will be kept in the location libraries, free for employee review.

IV. RECORD KEEPING AND REPORTING

- 1. Medical Records
 - a. Shall include: the name and social security number of the employee; a copy of the employee's hepatitis B vaccination status including the dates of all the hepatitis B vaccinations and any medical records relative to the employee's ability to receive vaccination; a copy of all results of examinations, medical testing, and follow-up procedures as required by this program; location's copy of the health care professional's written opinion as required in this program; and a copy of the information provided to the healthcare professional.
 - b. Employee medical records will be kept confidential and not disclosed or reported without the employee's express written consent to any person within or outside the workplace.
 - c. Medical records shall be kept for at least the duration of employment plus 30 years.
- 2. Training Records
 - a. Shall include the contents or a summary of the training sessions; names and qualifications of persons conducting the training; and names and job titles of all persons attending the training sessions.
 - b. Shall be maintained for 3 years from the date on which the training occurred.

V. SPECIAL PROVISIONS FOR HBV. These provisions apply if the Exposure Control Plan identifies that employees could be exposed to HBV during the course of their work.

- 1. Hepatitis B Vaccination
 - a. The location shall provide hepatitis B vaccinations (both initial and booster) to all employees who have occupational exposure to HBV, within 10 working days of initial assignment to the function which presents that occupational exposure, unless the employee has previously received the complete hepatitis B vaccination series,

antibody testing has revealed that the employee is immune, or the vaccine is contraindicated for medical reasons.

- b. These vaccinations are provided at no cost to the employee, performed at a reasonable time and place, and performed by or under the supervision of a licensed physician or another licensed healthcare professional.
- c. The location shall provide the vaccination to employees who initially decline hepatitis B vaccination but, at a later date while still covered under this plan, decide to accept the vaccination.
- d. Employees who decline to accept hepatitis B vaccination offered by the location must sign the following statement (the wording is mandatory): *I understand that due to my occupational exposure to blood or other potentially infectious materials I may be at risk of acquiring hepatitis B virus (HBV) infection. I have been given the opportunity to be vaccinated with hepatitis B vaccine, at no charge to myself. However, I decline hepatitis B vaccination at this time. I understand that by declining this vaccine, I continue to be at risk of acquiring hepatitis B, a serious disease. If in the future I continue to have occupational exposure to blood or other potentially infectious materials and I want to be vaccinated with hepatitis B vaccine, I can receive the vaccination series at no charge to me.*

2. Hepatitis B Post-Exposure Evaluation and Follow-up

- a. The location shall also make available post-exposure medical evaluation and follow-up to all employees who have had an exposure incident. These evaluations and follow-ups are confidential, and they are provided at no cost to the employee, performed at a reasonable time and place, and performed by or under the supervision of a licensed physician or another licensed healthcare professional.
- b. The medical evaluation and follow-up shall include at least the following elements:
 - 1) Documentation of the route(s) of exposure, the circumstances under which the exposure incident occurred, and identification and documentation of the source individual, unless the laboratory can establish that identification is infeasible or prohibited by state or local law.
 - 2) Collection and testing of the employee's blood for HBV and HIV serological status as soon as feasible after consent is obtained.
 - 3) Post-exposure prophylaxis, when medically indicated, as recommended by the U.S. Public Health Service.
 - 4) Counseling.
 - 5) Evaluation of reported illnesses.
- c. The location shall provide the following information to the healthcare professional evaluating an employee after an exposure incident:
 - 1) A copy of 29 CFR 1910.1030.

- 2) A description of the exposed employee's duties as they relate to the exposure incident.
 - 3) Documentation of the route(s) of exposure and circumstances under which exposure occurred.
 - 4) Results of the source individual's blood testing, if available.
 - 5) All medical records relevant to the appropriate treatment of the employee including vaccination status which are the location's responsibility to maintain.
- d. The healthcare provider shall provide written report. It shall be limited to whether a Hepatitis B vaccination is indicated for the employee and if the employee has received such vaccination. The report should also indicate that the employee has been informed of the results of the evaluation and been told about any medical conditions resulting from exposure to blood or other potentially infectious materials which require further evaluation or treatment. All other findings or diagnoses shall remain confidential and shall not be included in the written report. Within 15 days after receiving the healthcare professional's completed evaluation, the location shall provide it to the affected employee.

APPENDIX 5.1

Biosafety Level 2 Laboratory Criteria

LABORATORY FACILITIES

The laboratory is designed and maintained so that it can be easily cleaned.

Bench tops are impervious to water and resistant to acids, alkalis, organic solvents, and moderate heat.

Laboratory furniture and facilities are sturdy, and the areas between them are easily accessible for cleaning.

Each laboratory contains a sink for hand washing.

Autoclaves for decontaminating infectious laboratory waste are available.

Provide lockable doors for facilities that house restricted agents (as defined in 42 CFR 72.6).

Consider locating new labs away from public areas.

Install biological safety cabinets in such a manner that fluctuations of the room supply and exhaust air do not cause the biological safety cabinets to operate outside their parameters for containment.

An eyewash station is readily available.

Illumination is adequate for all activities, avoiding reflections and glare that could impede vision.

APPENDIX 5.2

Biosafety Level 2 Laboratory Criteria

STANDARD MICROBIOLOGICAL PRACTICES

Access to the laboratory is restricted or limited when work with infectious agents is being done.

Work surfaces are decontaminated at least daily and after any spill of viable material.

Infectious liquid or solid wastes are decontaminated before disposal.

Mechanical pipetting devices are used, and mouth pipetting is prohibited.

Eating, drinking, smoking, and applying cosmetics are not permitted in the work area.

Personnel wash their hands after handling infectious materials and animals and when they leave the laboratory.

All procedures are performed carefully to minimize the creation of aerosols.

Food is stored outside the work area in cabinets or refrigerators designated for this purpose only.

Policies for the safe handling of sharps is instituted.

An insect and rodent control program is in effect.

APPENDIX 5.3

Biosafety Level 2 Laboratory Criteria

SPECIAL PRACTICES and SAFETY EQUIPMENT (Primary Barriers)

Contaminated materials that are to be decontaminated at a site away from the laboratory are placed in a durable, leakproof container which is closed before being removed from the laboratory.

Personnel with health status such that they are at increased risk of acquiring infection or for whom infection may be unusually hazardous are kept from the laboratory.

Access to the laboratory is limited to personnel who have received training in potential biohazards, special procedures, and entry requirements.

When infectious agents in use in the laboratory require special provisions for entry, signs are posted on the access doors.

Insects and rodents are effectively controlled to minimize potential spread of infectious organisms.

Laboratory coats, gowns, or smocks are worn in the laboratory when working directly with infectious agents. Before leaving the laboratory, the protective clothing is removed and left in the laboratory or covered with a clean coat not used in the laboratory.

Animals not involved in the work being performed are not allowed in the laboratory.

Gloves are worn when skin contact with infectious agents or infected animals is likely.

All potentially infectious laboratory waste is appropriately decontaminated before disposal.

Hypodermic needles are used in a fashion to limit the possibility of autoinoculation or aerosol formation. Needles should not be bent, sheared, or removed from the syringe following use. The needle and syringe should be promptly placed in a puncture resistant container and decontaminated.

Spills and accidents which result in overt exposures to infectious materials are immediately reported to the BSO, immediate supervisor, and/or Research Leader. Medical evaluation, surveillance, and treatment are provided as appropriate and written records are maintained.

Biological safety cabinets, other physical containment devices, and/or personal protective equipment are utilized when:

- a. Procedures with a high potential for creating infectious aerosols are conducted.
- b. High concentrations or large volumes of infectious agents are used.

Properly maintained biological safety cabinets, preferably Class II, or other appropriate personal protective equipment or physical containment devices are used whenever:

- a. Procedures with a potential for creating infectious aerosols or splashes are conducted.
- b. High concentrations or large volumes of infectious agents are used.

Face protection is used for anticipated splashes or sprays.

Protective lab coats, gowns, smocks, or uniforms designated for lab use are worn while in the lab.

Gloves are worn when hands may contact potentially infectious materials, contaminated surfaces or equipment.

Gloves are disposed of when overtly contaminated, and removed when work with infectious materials is completed or when the integrity of the glove is compromised.

APPENDIX 5.4

Appendix to 42 CFR Part 72 - Select Agents

Viruses:

Crimean-Congo haemorrhagic fever virus
Eastern Equine Encephalitis virus
Ebola viruses
Equine Morbillivirus
Lassa fever virus
Marburg virus
Rift Valley fever virus
South American Haemorrhagic fever viruses (Junin, Machupo, Sabia, Flexal, Guanarito)
Tick-borne encephalitis complex viruses
Variola major virus (Smallpox virus)
Venezuelan Equine Encephalitis virus
Viruses causing hantavirus pulmonary syndrome
Yellow fever virus

Exemptions: Vaccine strains of viral agents (Junin Virus strain candid #1, Rift Valley fever virus strain MP-12, Venezuelan Equine encephalitis virus strain TC-83, Yellow fever virus strain 17-D) are exempt.

Bacteria:

Bacillus anthracis
Brucella abortus, *B. melitensis*, *B. suis*
Burkholderia (Pseudomonas) mallei
Burkholderia (Pseudomonas) pseudomallei
Clostridium botulinum
Francisella tularensis
Yersinia pestis

Exemptions: vaccine strains as described in Title 9 CFR, Part 78.1 are exempt.

Rickettsiae:

Coxiella burnetii
Rickettsia prowazekii
Rickettsia rickettsii

Fungi:

Coccidioides immitis

Toxins:

Abrin
Aflatoxins
Botulinum toxins

Clostridium perfringens epsilon toxin
Conotoxins
Diacetoxyscirpenol
Ricin
Saxitoxin
Shigatoxin
Staphylococcal enterotoxins
Tetrodotoxin
T-2 toxin

Exemptions: Toxins for medical use, inactivated for use as vaccines, or toxin preparations for biomedical research use at an LD50 for vertebrates of more than 100 nanograms per kilogram body weight are exempt. National standard toxins required for biologic potency testing as described in 9 CFR Part 113 are exempt.

Recombinant organisms/molecules:

Genetically modified microorganisms or genetic elements from organisms on Appendix A, shown to produce or encode for a factor associated with a disease.

Genetically modified microorganisms or genetic elements that contain nucleic acid sequences coding for any of the toxins listed in this Appendix, or their toxic subunits.